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PRECICE® Trauma Nail System
510(k) Summary – K TBD
May 2014

1.	**Company:**	Ellipse Technologies, Incorporated 13900 Alton Parkway, Suite 123 Irvine, CA 92618
	Contact:	Rebecca Shelburne Regulatory Affairs Specialist Phone: (949) 837-3600 x227 Fax: (949) 837-3664
	Date Summary Prepared:	May 29, 2014
2.	**Proprietary Trade Name:**	PRECICE Trauma Nail System
3.	**Common Name:**	Intramedullary Nail
4.	**Classification Name:**	Intramedullary Fixation Rod (21 CFR 888.3020)
5.	**Product Code:**	HSB (Rod, Fixation, Intramedullary and Accessories)

6. Product Description: The Ellipse PRECICE Trauma Nail System is composed of the modified PRECICE Nail (supplied sterile), locking screws, surgical instruments and an external remote controller (ERC). The Nail is available in various diameters, lengths and screwhole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters and lengths. The modified PRECICE Nail is supplied sterile by gamma radiation while the locking screws and accessories are supplied non-sterile and must be sterilized prior to use. The Nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. The Nail is supplied pre-distracted by 10 mm to allow for compression fracture reduction techniques.

7. Indications: The Ellipse PRECICE Trauma Nail System is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

8. Substantial equivalence: A detailed comparison to the predicate device demonstrates that the Ellipse PRECICE Trauma Nail System is substantially equivalent to the following 510(k) cleared device:

Trade Name:	PRECICE® Trauma Nail System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K113695

Substantial equivalence is based on identical indications for use, designs, and on *in vitro* testing performed.

The modified PRECICE Trauma Nail System and the predicate PRECICE Trauma Nail System have the same intended use. Specifically, the device is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones. In addition to the indication, the

principles of operation for the modified PRECICE Trauma Nail System are the same as that of the predicate PRECICE Trauma Nail System. The devices are inserted into the intramedullary canal of the bone and secured with locking screws. These devices contain an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. They both can be adjusted non-invasively by the Ellipse external remote controller (ERC).

The differences between the modified PRECICE Trauma Nail System and the predicate PRECICE Trauma Nail System are as follows:

- The design of the Nail has been modified to incorporate the design changes made to the PRECICE Intramedullary Limb Lengthening System.
- The addition of an 8.5 mm diameter nail in the PRECICE Trauma Nail System product offerings.

The design of the modified PRECICE Trauma Nail is identical to the PRECICE Nail in the PRECICE Intramedullary Limb Lengthening System, with the only difference being that the PRECICE Trauma Nail is supplied pre-distracted by 10 mm to allow for compression fracture reduction techniques. The modified PRECICE Trauma Nail has the same materials, technological characteristics and principles of operation as that of the modified PRECICE Nail in the referenced PRECICE Intramedullary Limb Lengthening System. Because the design of these two systems are identical, the following tests that were performed on the referenced PRECICE Intramedullary Limb Lengthening System also applies to the PRECICE Trauma Nail System that is subject of this premarket notification:

- Mechanical Testing
- Design Verification Testing
- Magnetic Field Safety Testing
- Packaging and Shelf-life Validation
- Sterilization Validation
- Biocompatibility Testing

Conclusions can be drawn that the modifications to the PRECICE Trauma Nail in the PRECICE Trauma Nail System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

Ellipse Technologies, Incorporated
Ms. Rebecca Shelburne
Regulatory Affairs Specialist
13900 Alton Parkway, Suite 123
Irvine, California 92618

Re: K141447
Trade/Device Name: PRECICE® Trauma Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 29, 2014
Received: June 2, 2014

Dear Ms. Shelburne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141447

Device Name
PRECICE® Trauma Nail System

Indications for Use *(Describe)*
The Ellipse PRECICE Trauma Nail System is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices